

**EFFECTIVENESS OF TUBERCULOSIS
MEDICATION THERAPY ADHERENCE CLINIC
(TB-MTAC) AT KMCH**



*Dissertation Submitted to
The Tamil Nadu Dr. M.G.R. Medical university, Chennai, in
partial fulfilment for the requirement of the Degree of*

**MASTER OF PHARMACY
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Submitted by

Reg. No: 261640606

**Under the Guidance of
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CERTIFICATE

This is to certify that the research work entitled **“EFFECTIVENESS OF TUBERCULOSIS MEDICATION THERAPY ADHERENCE CLINIC AT KMCH”** was carried out by **Reg. No: 261640606**. The work mentioned dissertation was carried out at the Department of Pharmacy Practice, KMCH College of Pharmacy, Coimbatore, Tamilnadu under the guidance of **Dr. C. Dhandapani , M.Pharm., Ph.D** , for the Partial fulfilment for the degree of Master of Pharmacy during the academic year 2017-2018 and is forwarded to the Tamilnadu Dr. M.G.R. Medical University, Chennai.

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CERTIFICATE

This is to certify that the dissertation work entitled **“EFFECTIVENESS OF TUBERCULOSIS MEDICATION ADHERENCE THERAPHY CLINIC AT KMCH”** is a bonafide work carried out by **Reg. No: 261640606**. The work mentioned in the dissertation was carried out at the Department of Pharmacy Practice, KMCH College of Pharmacy, Coimbatore, Tamilnadu, under my supervision and guidance during the academic year 2017-2018. This research work in part or full does not constitute any of any thesis/ dissertation.

Signature

Dr. C. DHANDAPANI, M.Pharm., Ph.D

Date:

Place: Coimbatore

DECLARATION CERTIFICATE

I do hereby declare that the dissertation work entitled “**EFFECTIVENESS OF TUBERCULOSIS MEDICATION THERAPY ADHERENCE CLINIC AT KMCH**” submitted to The Tamil Nadu Dr. M.G.R. Medical University, Chennai, in partial fulfilment for the Degree of **MASTER OF PHARMACY**, in **Pharmacy Practice**, was carried out at Department of Pharmacy Practice, KMCH College of Pharmacy, Coimbatore , under the guidance of Dr. C. DHANDAPANI, M.Pharm, Ph.D, during the academic year 2017-2018.

Signature

Date:

Place:

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EVALUATION CERTIFICATE

This is to certify that the dissertation work entitled “**EFFECTIVENESS OF TUBERCULOSIS MEDICATION THERAPY ADHERENCE CLINIC AT KMCH**” submitted by **Reg. No: 261640606**, to The Tamil Nadu Dr. M.G.R. Medical University, Chennai, in partial fulfilment for the Degree of **MASTER OF PHARMACY** in **PHARMACY PRACTICE** is a bonafide work carried out by the candidate during the academic year 2017-2018 at KMCH College of Pharmacy, Coimbatore, Tamil Nadu and the same was evaluated by us.

Examination Centre: Department of Pharmacy Practice, Coimbatore

Date:

Internal Examiner:

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ABBREVIATIONS

ADR	- Adverse Drug Reaction
ADA	- Adenosine Deaminase
AIDS	- Acquired Immunodeficiency Syndrome
ATT	- Anti Tubercular Therapy
DOTS	-Directly Observed Therapy Short Course
DR	– Drug Resistance
EMB	- Ethambutol
EPTB	– Extra Pulmonary Tuberculosis
FDA	– Food And Drug Administration
INH	– Isoniazid
LTBI	– Latent Tuberculosis Infection
MDR-TB	– Multi Drug Resistant Tuberculosis
PZA	– Pyrazinamide.
RBT	- Rifabutin
RPT	- Rifapentine
RIF	– Rifampin
RNTCP	– Revised National Tuberculosis Control Program
SSM	– Sputum Smear Microscopy
TB	– Tuberculosis

TST	– Tuberculin Skin Test
WHO	– World Health Organisation
XDR-TB	- Extensively Drug-Resistant Tuberculosis

INTRODUCTION

Tuberculosis (TB) is the most preventable human infection and cause more deaths worldwide than any other infectious disease. Tuberculosis (TB) is the leading communicable disease among the ten cause of the global mortality. It caused by tubercle bacillus, known as *Mycobacterium tuberculosis*, and more rarely mycobacterium bovis whose host is human. It¹ typically affects the lungs(pulmonary TB) but can also affect other parts as well(extra pulmonary), it transmitted by air droplets of people with the active tuberculosis TB.²

Sign and symptoms of TB

To an extent, the sign and symptoms of active TB depends on the location of affected. TB disease affect mainly in respiratory illness, but it can develop other body site. The sites other than respiratory where TB can affect

Peripheral lymph nodes (TB lymphadenitis)

Central nervous system (TB meningitis, Tuberculoma)

Abdominal cavity

Genitourinary system

Bones and joints

Generalised symptoms of TB diseases includes

- Fever
- Night sweats
- Weight loss/ loss of appetite
- Fatigue

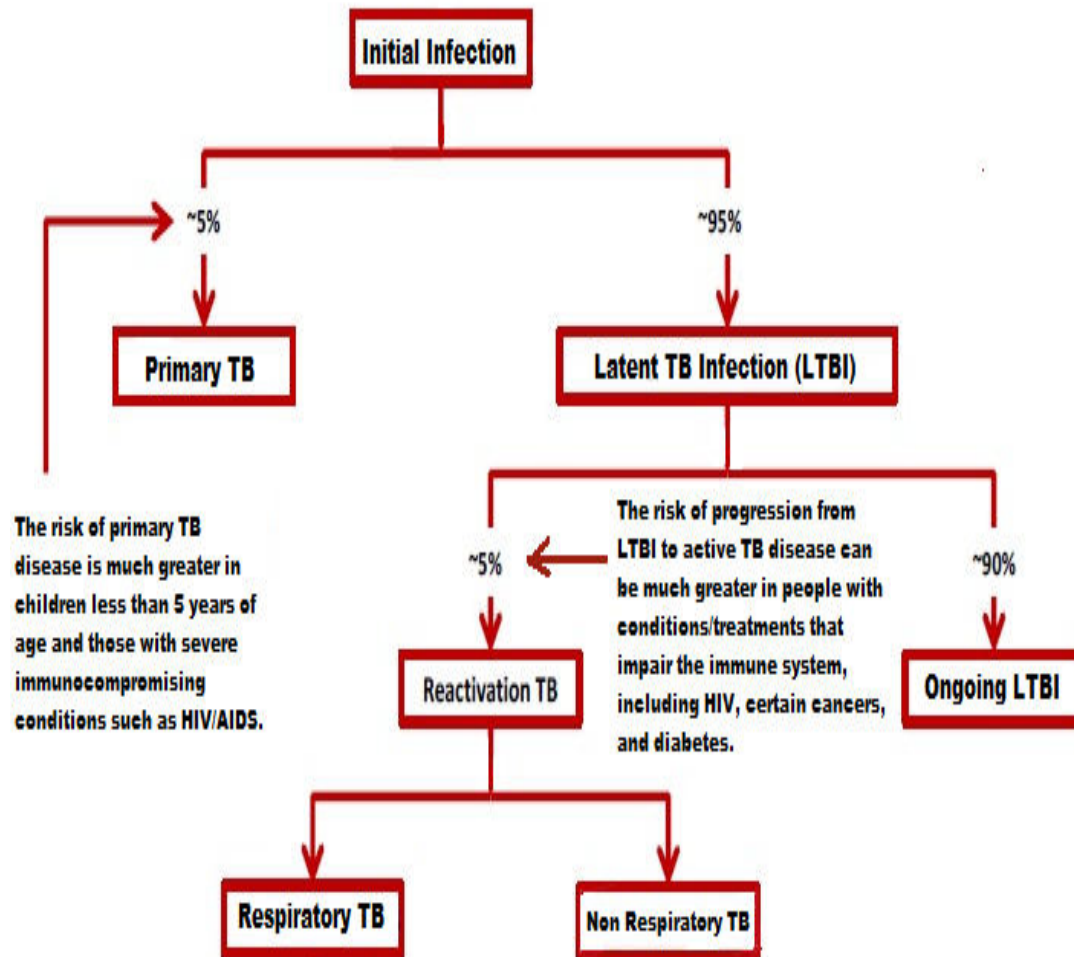
Symptoms and sign of TB in lungs includes:

- Cough of at least 2 to 3 week
- Chest pain
- Haemoptysis (blood in sputum)³

Transmission

Mycobacterium tuberculosis is spread by small airborne droplets in most cases (97%), called droplet nuclei, generated by the coughing, sneezing, talking, or singing of a person with pulmonary or laryngeal tuberculosis. These virulent bacilli once inhaled will stay in the pulmonary alveoli, where they will be phagocytosed (to envelop and destroy bacteria and other foreign materials). It is the primary infection may be asymptomatic. Once infectious particles are aerosolized, they are spread throughout a room or building by air currents and can be inhaled by another individual. One droplet nuclei contains no more than 3 bacilli. Droplet nuclei are so small that they can remain air-borne for extended periods of time. Introduction of *M tuberculosis* into the lungs leads to infection of the respiratory system; however, the organisms can spread to other organs, such as the lymphatics, pleura, bones/joints, or meninges, and cause extrapulmonary tuberculosis.⁴

Pathogenesis of TB



The likelihood of and timing for developing active TB disease after becoming infected with TB bacteria is highly variable. Some people, particularly young children and those with advanced immune suppression (e.g., HIV/AIDS) are highly susceptible to developing TB disease soon afterward (primary TB disease).

The majority (95%) of healthy people over 5 years of age who become infected with TB bacteria develop latent TB infection (LTBI). Of these, a small percentage (5%) will eventually develop

active TB disease. TB disease that develops after a period of LTBI is known as reactivation TB disease. Reactivation TB disease is more likely to occur when a person with LTBI is or becomes immune suppressed.⁵

Diagnosis of TB

Active TB disease can be difficult to diagnose, especially in children and those who have weakened immune systems, additional tests beyond medical examinations are required. The following tests may be used to determine if a patient has active TB disease:

- Tuberculin Skin Test (TST)
- Chest Radiograph (X-ray)
- Sputum Smear Microscopy (SSM)
- Culture
- Polymerase Chain Reaction (PCR)
- Ultrasound
- Adenosine Deaminase (ADA)
- Erythrocyte Sedimentation Rate (ESR)
- TB LAM (lateral flow version) ⁶

Treatment

Drug treatment is the keystone of tuberculosis management. When active disease is present, a bare of minimum 2 drugs and generally 3 or 4 drugs must be used simultaneously.⁷ The duration of treatment depends on the condition of host, extent of disease, presence of drug resistance and tolerance of medication. The shortest duration of treatment is generally 6 month, and 2 to 3

years of treatment is necessary for cases of multi drug resistance TB (MDR – TB) . As it long term vigilant follow up is required to improve the treatment outcome.⁸

FDA approved TB treatment drugs, isoniazid (INH), rifampin (RIF), ethambutol (EMB), and pyrazinamide (PZA) are considered first-line anti-TB drugs and form the core of standard treatment regimens. Rifabutin (RBT) and rifapentine (RPT) may also be considered firstline drugs under certain circumstances. RBT is used as a substitute for RIF in the treatment.⁹ Amikacin and kanamycin, nearly identical aminoglycoside drugs used in treating patients with TB disease , are not approved by the FDA for treatment of TB. These drugs are reserved for special situations such as drug intolerance or resistance.¹⁰

Directly Observed Therapy (DOT)

DOT is a component of case management that helps ensure patients adhere to therapy. It is the method whereby a trained health-care worker or another trained designated person watches a patient swallow each dose of anti-TB drugs and documents it. DOT is the preferred core management strategy recommended for treatment of TB disease and, if resources allow, for latent tuberculosis infection (LTBI) treatment. DOT can reduce the development of drug resistance, treatment failure, or relapse after the end of treatment. Good case management, which includes establishing a relationship with the patient and addressing barriers to adherence, facilitates successful DOT.¹¹ Nearly all the treatment regimens for drug-susceptible TB disease can be given intermittently if they are directly observed. Using intermittent regimens reduces the total number of doses a patient must take, as well as the total number of encounters with the health-care provider or outreach worker, making these regimens more cost-effective. Drug resistant TB disease should always be treated with a daily regimen and under direct observation. There are no intermittent regimens for treatment of multidrug-resistant (MDR) TB.

If anti-TB drugs for the treatment of MDR TB need to be given twice daily, then DOT should be provided twice daily as well.¹²

Drug resistant Tuberculosis (MDR-TB & XDR-TB)

The bacteria that cause TB can develop resistance to the antimicrobial drugs used to cure the disease. Multidrug-resistant TB (MDR-TB) is TB that does not respond to at least isoniazid and rifampicin, the two most powerful anti-TB drugs. The reasons why multidrug resistance continues to emerge and spread are mismanagement of TB treatment and person-to-person transmission. Most people with TB are cured by a strictly followed, six-month drug regimen that is provided to patients with support and supervision. Inappropriate or incorrect use of antimicrobial drugs, or use of ineffective formulations of drugs (e.g. use of single drugs, poor quality medicines or bad storage conditions), and premature treatment interruption can cause drug resistance.¹³ Extensively drug-resistant TB, (XDR-TB) is a form of multi drug resistant TB with additional resistance to more anti-TB drugs that therefore responds to even fewer available medicines.¹⁴

BACKGROUND

Estimates show that approximately one third of global population of the world continuously infected with Tuberculosis. The World Health Organisation (WHO) reported that, TB is almost exclusively a disease of the developing countries.¹⁵ According to World health organisation (WHO), by the end of 2020, nearly one billion people will newly infected, 200 million people get sick and 35 million will die from tuberculosis, if control is not further strengthened¹⁶

Every day in India, under the Revised National TB Control Programme (RNTBCP), more than 15,000 people were examined. Estimate suggest that two persons die every three minutes due to tuberculosis and 5000 new cases TB cases are diagnosed per day. A single patient can infect 10-

15 people in a year.¹⁷ The availability of effective treatment, TB still a major health problem in most countries. The poor outcome was accredited to **poor adherence**, and partly due to **adverse drug reaction**. Non-compliance is cited as a major obstacle to the control of tuberculosis at the level of public health. It is also a serious problem in the treatment of individual patients and in the development of drug resistant strains.¹⁸

Medication adherence/ compliance are similar terms. Compliance is extended to which the patient's medication taking behaviour coincides with medical or health advice; and persistence as the duration of time from initiation to discontinuation of therapy.¹⁹ Non-adherence to TB treatment leads to high increase in morbidity and mortality, prolonged TB infectiousness, multi drug resistance, relapse and death. The patient with adherence level greater than 90% facilitates cure. The failure of cure increases the risk of development of drug resistant strains and further spread TB in the community.²⁰

After several decades of research show that medication non-adherence is due to many factors including lack of adequate knowledge about medication and treatment goals, beliefs about medication, complex regimes that are difficult to manage, side effects and costs associated with medications.²¹

According to World Health Organisation, the reason for poor compliance with anti-tuberculosis treatment in developing countries are complicated.²² that includes; the characteristics of the individual patient, communication between the patients and healthcare providers, social and economic factors such as availability of drug, duration and number of medication, side effects, cost of treatment, competing demands on time²³. However, patient adherence to tuberculosis

treatment require the active participation of the patient in self management of treatment and cooperation between patient and the health care provider.²⁴

ROLE OF PHARMACIST IN ATT-AS A PART OF HEALTH CARE TEAM

Educating patients about TB disease helps ensure their successful completion of therapy. Healthcare providers must take the time to explain clearly to patients what medication should be taken, how much, how often, and when. Patients should be clearly informed about possible adverse reactions to the medications they are taking and when to seek necessary medical attention. Providing patients with the knowledge they need regarding the consequences of not taking their medicine correctly is very important. In addition, patients should be educated about infection control measures and potential need for isolation.²⁵

All health care providers need to counsel TB patients not only the importance of taking their medication regularly but also on the importance of completing their course of treatment. Poor adherence with TB treatment is more dangerous than no treatment as it may increase the risk of developing multi drug resistant tuberculosis strains.²⁶

Patient understanding of their treatment regimen can influence their adherence behavior. Pharmacists can play a pivotal role in promoting patient adherence to drug therapy, which leads to optimization of drug therapy goals and outcomes.^(27, 28) As medication experts, pharmacists can utilize their clinical training to reduce drug interactions, optimize therapy for patients presenting resistant microbes, provide education on the importance of adherence to therapies, and make recommendations for therapy when necessary.²⁹

Here come the role of pharmacist. Clinical pharmacist has the responsibility to identify, prevent and resolve medication related problems. The services given by the clinical pharmacist include medication history interview, medication order review, providing drug information, assessment and management of drug interaction, patient medication counseling and management of ADR's which will improve patient compliance and reduce health care costs.³⁰

The pharmacist should educate patients on the importance of continuing their chemotherapy despite symptomatic improvement. Pharmacist should become a part of multidisciplinary band devoted to successful chemotherapy of TB patient and their families.³¹

LITERATURE REVIEW

- ***Xinji Gong, et al., (2018)*** conducted a study on “Treatment adherence among sputum smear-positive pulmonary tuberculosis patients in Xinjiang, China” it was a prospective study was conducted for total of 8289 sputum smear positive TB patients were included . Among 8289 patients, 3827 men (84.4% of male patients) and 3220 women (85.7% of female patients) had good adherence during treatment follow-up. 1242 patients (15.0%) did not complete regular follow-up. 332 (4.0%) patients lost contact. The concluded with supervision and interventions during the TB treatment process to improve patient adherence to anti-TB treatment ³²
- ***Jaramillo E, et al. (2018)*** conducted a study on “Adherence interventions and outcomes of tuberculosis treatment: A systematic review and metaanalysis of trials and observational studies.” in this 129 met the inclusion criteria for quantitative analysis. Seven adherence categories were identified the study concluded that, TB treatment outcomes are improved with the use of adherence interventions, such as patient education and counseling, incentives and enablers, psychological interventions, reminders and tracers, and digital health technologies. This concluded with Trained healthcare providers as well as community delivery provides patient-centered DOT options that both enhance adherence and improve treatment outcomes as compared to unsupervised,³³
- ***Aarsha Joby et al., (2017)*** conducted a study on the topic “Impact of pharmacist assisted Patient counseling For improving medication adherence and quality of life in pulmonary tuberculosis patient” it was a interventional

prospective study. In the study 164 patients enrolled there were 2 deaths and 5 drop outs. Among 157 patients , 37 were found to be a adherent 20 were at the risk of non-adherence and 100 were found to be non adherent. The study concluded that , pharmacist assisted patient counseling had a significant impact in improving medication adherence and QOL in pulmonary tuberculosis patients.³⁴

- **Khairunnisa et al.,(2017)** conducted a study on the topic “ Pharmacist’s perception about their roles in tuberculosis control program in medan, Indonesia” in this study involved 117were asked to choose answering yes, no or do not know for their perception on their roles in TB control program. . Mean age of the participants was 38.6 ± 11.7 (years). Most of them were female. Distribution of the participants by place of practice: Pharmacy, 78.6%; hospital, 20.5%. Most of them (63.2%) have heard about directly observed treatment short-course program. More than 90% of them realized that they could play their roles as providers, managers of anti-TB drugs, drug informants, ensurers for adherence to the TB treatment, educators for patients and publics on TB and its treatment. Only 26.5% of them knew that they could also play their role as inventors of early suspected TB in the community. The study Concluded that, pharmacists’ roles could be utilized and enhanced to optimize TB control programs in Indonesia.³⁵
- **Aline Ale Beraldo et al., (2017)** conducted a study on” Adherence to tuberculosis treatment in Primary Health Care: perception of patients and professionals in a large municipality” it was a Cross-sectional epidemiological study conducted at the PHC of Campinas-SP, through structured interviews

with 18 corresponding questions on the perception of professionals (183) and patients (165). The study Concluded that, The identification of gaps in the offer of actions for adherence to TB treatment can help health services to change and improve the practice and the epidemiological scenario of the disease.³⁶

- **Rohit et al., (2017)** conducted a study on “Determine the factors influencing DOTS Compliance among tuberculosis patients of selected DOTS Centers of Ludhiana, Punjab.” the study carried out in selected DOTS centers. Total 110 tuberculosis patients taking DOTS were chosen by Purposive sampling technique. Self structured checklist was used to determine the factor influencing DOTS compliance among tuberculosis patients. It concluded that self motivational factor had the highest influence on compliance to DOTS but economical factors were influenced not to comply with DOTS and in context to factors compliance, it was not affected by socio demographic variables.³⁷
- **Harshul Gohel et al., (2017)** conducted a study on “A Cross Sectional Study to Assess the Non-Adherence to Anti-Tuberculosis Treatment and Determinant Factors among Patients with Pulmonary Tuberculosis” in this adherent and non-adherent patients randomly selected from government hospital and private hospital were interviewed using pre structured questionnaires most frequently mentioned reason for non-adherence to treatment was taking treatment from government hospital. The study indicated that patients who had low level of education, frequently travelling were showing non- adherent to treatment. Treatment adherence of TB patients receiving treatment in private hospital might be improved by providing health education about treatment duration and

side effects, facilitating procedures for receiving treatment free of charge and reducing costs of transportation and consultation. Qualified friendly health care staff able to motivate patients might further improve adherence in government hospital.³⁸

- ***Andrés Noe et al., (2017)*** conducted a study on” Knowledge, attitudes and practices regarding tuberculosis care among health workers in Southern Mozambique”it was a descriptive cross-sectional study was performed through the use of a specifically designed Knowledge, Attitudes and Practices (KAP) questionnaire. the study concluded that, present study provides impetus for tailored TB education among health care workers from a high TB burden rural area in Southern Mozambique.³⁹
- ***Richard Kiplangat Arap Sang et al., (2017)*** conducted a study on “Patient Factors Which Contribute to Non-adherence to TB Treatment in Kericho and Nakuru Counties of Kenya” The study concludes that Patient factors leading to non adherence range from Feeling well soon after medication, Alcoholism, self-denial, Drug side effects, pill burden, lack of food and low educational level. These are factors that are patient centered. Solution lies in patient Health Education that will lead to behaviour change that directly affects the patient’s adherence to Tuberculosis treatment.⁴⁰
- ***S. O. Oyugi et al.,(2017)*** conducted a study on Patient factors influencing adherence to anti-tuberculosis medication in njoro sun county hospital, keneya” In this study 25 patients analyzed. The study concluded that, t about a quarter of patients in TB treatment program will at one point miss some pills

either due to Conflict with work schedule, poor relationship between patients and Health Care Providers and alcoholic.⁴¹

- ***Siddiqua Aamiret al., (2016)*** conducted a study on “Role of Counselling to Facilitate Compliance to the Dots for the Treatment of Tuberculosis” in the study included 60 patient diagnosed with pulmonary tuberculosis. The sampling technique was used for the assignment of the patients to the experimental group (n= 30) and a control group (n=30). The results indicated that the majority of the experimental group patients adhered to the therapy. The study Concluded that, Counseling of patients is important to optimize therapy, aid compliance and to inform patients’ of any potential complications of therapy.⁴²
- ***Vijayalakshmi et al. (2016)*** conducted a study on “A prospective study on abnormal liver function test patterns in patients receiving anti-tubercular therapy” in this study assessed the incidence and risk factors of anti-TB-DIH . the patient enrollment was 63 are males and 37 are females, results shows that, Comparison between before treatment and 2 months treatment showed a significant increase. study concluded that, Anti-TB-DIH is not uncommon, needs early recognition and treatment and is more in patients with pre-existing liver disease and lower body mass index. in the level of aspartate amino transferase (AST), alanine amino transferase (ALT), and alkaline phosphatase (ALP).⁴³
- ***Yohannes Zenebe et al., (2016)*** conducted a study on “Profile of tuberculosis and its response to anti-TB drugs among tuberculosis patients n treated under

the TB control program at Felege-Hiwot Referral Hospital, Ethiopia” in this analyzed the records of 1761 TB patients registered for treatment. And Concluded that, In the studied region, the overall treatment success rate was still below the WHO target of success rate, 85 %. However, the trend of treatment success rate showed a promising increment. Patients at high risk of unsuccessful treatment outcome should be identified early and given additional follow-up, medical interventional social support.⁴⁴

- ***Stephanie Lin et al.,(2016)*** conducted a study on “Systematic review of risk factors for non adherence to TB treatment in immigrant populations “in this 1761 studies identified in the search, 20 were included in the risk factor review. Undocumented immigration status, older age, and social risk factors were consistently correlated with non adherence gender, ethnicity, immigration time, education level, adverse side effects, and HIV status were inconsistently correlated; and behavioural risk factors and marital status were consistently not correlated. Which concluded, the review emphasizes documentation status as a risk factor candidate for further investigation. ⁴⁵
- ***Shrishail S Patil et al., (2016)*** conducted a study on “A Study on Assessment of Patients Health Related Quality of Life During Tuberculosis Treatment in Tertiary Care Teaching Hospital”. the study was conducted for total 70 patients (56 men and 14 women) diagnosed with tuberculosis. A total of 70 patients completed the SF-36v2 questionnaire at the start of their treatment. Out of these, 53 and 41 completed the questionnaire at the second and third follow-ups, respectively. The study concluded with HRQoL improved with the treatment, the scores on component summary measures revealed the

improvement of both physical and mental health among study patients at the end of intensive phase.⁴⁶

- ***Daniel Fleissner et al., (2016) conducted a study on “The Impact of Pharmacist-Delivered Patient Education on Tuberculosis Drug Therapy Adherence”.*** The study concluded that pharmacist-led patient education and therapy monitoring increase adherence to prescribed treatment regimens and treatment completion rates.⁴⁷
- ***Jeremiah Chakaya et al.,(2016)***conducted a study on “Long term complications after completion of pulmonary tuberculosis treatment” the study concluded that, the long term complications that follow treatment of pulmonary TB is long overdue and will significantly contribute to the quality of care for TB patients. In many PTB patients successful completion of TB treatment or bacteriological cure is not the end of the need for care.⁴⁸
- ***Evans Dans et al., (2015)*** conducted a study on “ Patients’ Compliance with Tuberculosis Medication in Ghana Evidence from a Periurban Community” this study focused on Wide disparity in background characteristics between patients and their treatment supporters can affect acceptance of health directives provided by the treatment supporter. The results show that males who were previously treated were more than females . this study concluded with treatment supporters should be galvanized more in order to ensure a better control of the disease. Patients’ noncompliance with medication in the district is an issue and requires new approaches to solve the problem²⁷

- ***Muhammad Atif, et al., (2014)*** conducted a study on Impact of tuberculosis treatment on health-related quality of life of pulmonary tuberculosis patients. This was a prospective follow-up of new smear positive PTB patients who were diagnosed at the chest clinic of Penang General Hospital between March 2010 and February 2011. All eligible patients (i.e., a new case of smear positive PTB, literate and aged 18 years or above) were asked to self-complete the SF-36v2 questionnaire at the start of their treatment, and then subsequently after the intensive phase and at the end of the treatment. A total of 216 patients completed the SF-36v2 questionnaire at the start of their treatment. The study concluded that the HRQoL improved with the treatment, the scores on component summary measures showed compromised physical and mental health among study patients even at the end of their TB treatment.¹⁷
- ***Mudegoudara Lingaraja et al., (2014)*** conducted a study on “A Study of Liver Function Tests Abnormalities in Tuberculosis Patients Under RNTCP-DOTS, VIMS Bellary”. The purpose of the study was to evaluate the incidence of drug induced hepatitis. enrolled of 107 patients, 56(52.33%) were males and 51(47.66%) were females. The study conclude that the incidence of DIH is more common in patients with malnutrition, old age and advanced pulmonary tuberculosis .⁴⁹
- ***Allumellu Venkatapaveen, et al.,(2013)*** conducted a study on the Topic “Assessment of clinical pharmacist intervention to improve compliance a health care outcomes of tuberculosis patients. The nine months prospective study was conducted and enrolled patients were randomly divided in to two groups i.e. Intervention and Control groups. Out of 120 patients enrolled, 114

patients completed the study. Among 114 patients 81 were males and 33 were females. Comparatively the knowledge and drug adherence score of the Pulmonary Tuberculosis (PTB) patients of intervention group shows more improvement from baseline to I and II Follow ups which is statistically significant than the control group. The study concludes that pharmacist provided patient education found to have significant influence on patients compliance and health care outcomes.¹⁹

- **Mukhtar A. Solliman et al(2012)** conducted a study on "Assessment of Knowledge towards Tuberculosis among general population in North East Libya" it was a cross sectional study and pre validated questionnaire consisting of 23 items was sent to 1500 residents among five cities This study reveals that knowledge towards TB within the population is poor. It is therefore suggested that specialized educational programs should be developed for community members to promote awareness towards TB.⁵⁰
- **Daftary, et al.,(2011)** Performed a study on "Adherence to treatment for latent tuberculosis infection. A systematic review of studies in the US and Canada" was undertaken to analyze measurement of adherence to treatment of LTBI (TLTBI), TLTBI completion rates, predictors of TLTBI adherence and TLTBI adherence interventions. Associations between adherence and patient factors, clinic facilities or treatment characteristics were found to be inconsistent across studies A 'one-size-fits all' approach to treatment for TLTBI adherence is not likely to succeed across all settings. Innovative approaches can inspire future interventions and suggest solutions for the current problems facing LTBI programs and their patients.⁵¹

- ***Monica G Amuha et al., (2009)*** conducted a study on “Non-adherence to anti-TB drugs among TB/HIV co-infected patients in Mbarara Hospital Uganda: Prevalence and associated factors”. The study select 140 participants. study concluded that, The prevalence of non-adherence was high. Patients that are on continuous phase of TB treatment should be supported to continue taking their drugs. In addition, patients that drink alcohol; smoke and those not on ART should be targeted with interventions to improve adherence ⁵²
- ***Salla A. Munro, et al., (2007)*** conducted a study on Patient Adherence to Tuberculosis Treatmentthis systematic review of qualitative studies was to understand the factors considered important by patients, caregivers and health care providers in contributing to TB medication adherence. The findings of review could help inform the development of patient-centred interventions and of interventions to address structural barriers to treatment adherence.⁵³

AIM

To study the effectiveness of tuberculosis medication therapy adherence clinic at KMCH

OBJECTIVE

- ☐ To assess the level of adherence of anti-TB treatment
- ☐ To identify factors associated with non-adherence
- ☐ To identify adverse effect or complication resulting from the anti-TB medication
- ☐ To educate and encourage patients/ caregivers on the appropriate use of anti-TB medication and self- care devices
- ☐ To increase patients adherence towards anti-TB medication

3. METHODOLOGY

STUDY DESIGN:

A hospital based prospective observational study

STUDY SITE:

The study was conducted at the Department of pulmonology, Kovai Medical Center and Hospital, a 750 bedded multi-disciplinary advanced super speciality hospital, Coimbatore, Tamil Nadu, accredited by National Accreditation Board for Hospitals and Health care.

STUDY PERIOD:

The study was conducted from the period from February 2018 to July 2018.

STUDY POPULATION:

A total

STUDY CRITERIA

Tuberculosis patients in department of medicine were enrolled in to the study by considering following inclusion and exclusion criteria

INCLUSION CRITERIA:

- ☐ Patients diagnosed with pulmonary tuberculosis and extra pulmonary tuberculosis
- ☐ Patient between 18 year to 80 year of age
- ☐ Patients with active or inactive tuberculosis taking anti-tuberculosis treatment

EXCLUSION CRITERIA:

- ☐ Patient referred to DOT's centre
- ☐ Patients with MDR TB

SOURCES OF DATA:

- ☐ Data collection form
- ☐ Treatment charts
- ☐ Medication adherence assessment questionnaires (MMAQ)
- ☐ Knowledge assessment questionnaires (KAQ)
- ☐ Patient information leaflet (PIL)

STUDY PROCEDURE

Implementation

A minimum of three session of TB-MTAC are required for every patient. Subsequent visit follow up after 3 sessions must be done when necessary for better understanding on medication therapy adherence.

Baseline visit: At the initial visit, the pharmacist will perform an initial assessment of the patient/caregiver. The initial assessment will entails the patient socio demographic characteristics.

Second Follow up: 15th day after the baseline visit.

Third Follow up: 30th day after second follow up.

Missed Appointment

Patient/caregiver will contacted by phone for appointment rescheduled.

RESULTS

The study was carried out in the Pulmonology department of Kovai medical center and hospital at Coimbatore, over a period of 6 months from February to July 2018. A total of 100 patients were enrolled in to the study. Out of which, 80 patients have completed the study. Of the whole population 52 (65%) were outpatients and 28 (35%) were inpatients [Tab 1, Fig 1]. Among the total population, 61 (76%) were male and 19 (24%) were females [Tab 2, Fig 2].it is found that males were more prone to tuberculosis when compared to females.

The age group analysis of entire population in the study shows that the most prominent group was '46-60' comprising of 33 (41%) patients. 20 (25%) were between the age group of '61-75' years of age; 18 (23%) were between the age group of '31-45'years of age; 9 (11%) were between the age group of '16-30years of age [Tab 3 Fig 3]. Over all the study shows that the most prominent age for the occurrence of TB was 46-60. Out of the study population, 41 (52%) patients were .having the smoking habit. 39 (48%) patients were non-smokers.[Tab 4 , Fig 4]. Among the total population 73 (91%) were married and 7(9%) patients were single. [Tab 5 , Fig 5]. Summarized forms of TB diagnosis of the study were illustrated in table [6] and figure [6]. 63 (78.8%) patients were diagnosed as pulmonary TB in the study population. Of the remaining patients in the study 11(13.8%) patient were found to have TB in Pleural, 3 (3.8%) patients were found to have TB in Meningitis, 2 (2.5%) patients were found to have TB in Rib, 1(1.2%) patients was found to have TB in lymph. It shows that when compared to EPTB,

PTB shows most occurrences.

Among the population of the study, 6(7.5%) of the patients having university education, 18 (22.5%) of the patients having pre-university education;31(38.8%)of the patients having school

level of education and 25(31.2%) of the patient were illiterate patients.[Tab.7, Fig 7]. Among the enrolled patients most of the patients were farmer 20 (25%) followed by daily wage 17(21.2%); in private service having 13(16.2%) of the patients; 11(13.8%) of the patients in business; 3 (3.8%) of the patient were students; 16 (20%) of the patient were unemployed .[Tab 8, Fig 8]

Out of the total study population, most of the patients 58 (72.5%) shows the symptom of persistent cough for many days followed by fever for 42 (52.5%) patients, 19 (24%) patients having haemoptysis chest pain for 24 (30%) patients, 30(38%) of them having symptom of loss of appetite , 32 (40%) patients shows weight loss, 27 (34%) patients showed breathing difficulty and 18 (23%) shows the other symptoms.[Tab 9, Fig 9].

Among the population most of the reason for non-adherence are forgetfulness 21(26.25%), 20 (25%) of them having feeling well, 13 (16.25%) of them reported phase of chemotherapy, 8(10%) patient reported side effects are reason for non-adherence, 10 (12%) reported additional drug is a factor for non-adherence, and the 8(10%) reported financial issue is reason for non-adherent. [Tab 10, Fig 10]. Among the study population 21 (26%) patients experienced at least one ADR during the time of study period [Tab 11, Fig 11]. Out of 21 ADR 8(38%) were elevated liver enzyme, which is most prominent followed by skin rash 6(28.6%), abdominal pain 3(14.3%), numbness of feet also 3(14.3%) and chest pain with 1(4.8%) patient. [Tab12, Fig 12].

The time interval between start of therapy and onset of ADR is given in the table [Tab 13, Fig 13] it found that 15(71.5%) ADR occurred within the first visit after starting the therapy, in second visit 4(19%) patients developed ADR and third visit 2(9.5%) patients developed. An overview shows that as there is a decreased incidence of ADRs when the days get increased.

All the 80 patients of the study were initially provided MAS questionnaires at the time of enrollment and subsequent follow up, medication adherence score was evaluated at baseline, first and second follow up. [Tab14, Fig 14]. The baseline adherence data was compared with first and second follow up adherence data using ANOVA.

The baseline with first follow up revealed a mean increase in medication adherence level of 1.95 ± 0.745 and ($P < 0.0001$) which is statistically significant.

Baseline adherence with second follow up adherence data shows a mean increase in medication adherence level of 2.14 ± 0.725 and ($P < 0.0001$) which is statistically significant. [Tab 15, Fig 15, Fig 16]. The association of demographic characteristics of the study with adherence score. [Tab.16] among them except education' all the characteristics statistically significant with Medication Adherence score at 0.05 significant levels. They include the participants' gender with P- value of .00, age group with P- value of .003, Type of TB with P- value of .000, Marital status with P value of .000, patient type with P value of .000, smoking habit with P value of .000, Occupation with P value of .000. these are significant association between adherence. There is no association between Adherence on level of educational respondents.

The knowledge score was evaluated at baseline, first and second follow up. [Tab 17, Fig 17]. The baseline knowledge data was compared with first and second follow up Knowledge data using ANOVA. The baseline knowledge with first follow up knowledge data shows a mean increase in knowledge level of 1.98 ± 0.675 and ($P = 0.021$) which is statistically significant. Baseline knowledge with second follow up knowledge data shows a mean increase in knowledge level of 2.40 ± 0.722 and ($P = 0.009$) which is statistically significant [Tab 18, Fig 18, Fig 19]. The result of analysis of the relationship between Knowledge on demographic characteristics of

respondents. [Tab19]. Among them, all the respondents statistically significant with the TB Knowledge at the 0.05 significant levels. Comparatively study of the knowledge and drug adherence score of the Tuberculosis patients shows more improvement from baseline to 1 and 2 follow ups ($P < 0.0001$). which is statistically significant.[Tab 20, Fig 20].

DISCUSSION

In the prospective study, A total of 80 patients were incorporated in the study. 61 (76.%) were male and 19 (24%) were females. It found that males more prone to tuberculosis when compared to females. A study conducted by *Mahmood et al.*, reveals that the pervasiveness of tuberculosis is more in males than females.⁹ Also a study performed by *JaggaraJamma k et al.*, has the identical outcome alike to this study in case of the gender wise occurrence of the TB, which contributes that a 7:2.5 ratio of males and females incidence of TB. Not only these studies some other studies also point out that the TB is more prone to male gender.⁵⁴

The age group analysis of the study shows that, 33 (41.2%) patients came under the age group of 46-60 years which indicate the occurrence of TB more in this age group. *Allumellu Venkatapraveen et al.*, observed that 27(24%) patients had TB in the age group of 51-60 years.¹⁹ A descriptive study executed by *Habibullah K et al.*, reveals that the age group of TB occurrence is 45-55 years. Both of these studies supporting to the current study outcome.⁵⁵ 63 (78.8%) patients were diagnosed as pulmonary TB in the study population. About 92% of the population in the research of *JggaraJamma K et al.*,⁵⁴ were diagnosed as PTB. A study reported by *S.Lakshmi Sabapathi1 et al.*, interpret that 74% of the study population were diagnosed PTB which is matching to this study.⁵⁶

Out of the total study population, most of the patients 58 (72.5%) shows the symptom of persistent cough for many days. About 83% of patients were having cough in the study done by *Bello and Itiola O A et al.*,¹ Among the population most of the reason for non-adherence are forgetfulness 21(26.25%). A study conducted by *S.Lakshmi Sabapathi1 et al.*, reveals that the 34% of patients shows the forgetfulness was a reason for non-adherence.⁵⁶ Some of the studies

also shows that the feeling well is a reason for non-adherence. 15(71.5%) ADR occurred within the first visit after starting the therapy , An overview shows that as there is a decreased incidence of ADRs when the days get increased. This is quite similar to the study *of Kheirollah G et al.*,⁵⁷

Medication adherence score was evaluated at baseline, first and second follow up. Baseline adherence with first follow up and second follow up adherence data shows a mean increase in medication adherence. It is very similar to the study conducted by *Alok bhardwaj et al.*,⁵⁸ and study conducted by *Allumellu Venkataprameen et al.*, The relationship between Adherence score and demographics, among them except education' all the characteristics statistically significant with Medication Adherence score at 0.05 significant levels. ¹⁹A study conducted by *Tesfahuneygn et al.*, reveals that the association of demographic and adherence score which shows there is no association between adherence and the respondents of educational status, marital status.⁵⁹ And the other respondents were significant with adherence score. The another study conducted by *Tola et al* observed that, the demographics sex, education level, marital status, economic status, knowledge level, and psychological distress were significant with adherence score. But the age analysis shows there is no association between the adherence score.⁶⁰

The knowledge score was evaluated at baseline, first and second follow up. A study conducted by *Allumellu Venkataprameen et al.*, which also similar to current study.¹⁹ *Lekhraj Rampal et al.*, conducted a study similar to this study.⁶¹The result of analysis of the relationship between Knowledge on demographic characteristics of respondents. Among them, all the respondents statistically significant with the TB Knowledge. A study conducted by *Nwankwo Mercy Chineye et al.*, which show that the Knowledge relationship with socio-demographics

characteristics, among them were three that were statistically significant with knowledge at the 0.05 significant level.⁶² Another study conducted by *Kelemework Abera et al.*, which has the identical outcome alike to this study.⁶³

Comparatively the knowledge and drug adherence score of the Tuberculosis patients shows more improvement from baseline to 1 and 2 follow ups ($P < 0.0001$). which is statistically significant. Similar study was carried out by *Allumellu Venkatapaveen et al.*, in this study patient had higher score in knowledge and adherence.¹⁹ Another study conducted by *Gabrieia fagundez et al.*, which is similar to this study.⁶⁴

TABLES AND GRAPHS

TABLE1: WARD WISE DISTRIBUTION OF TOTAL PATIENTS (n=80)

Type of patient	Frequency	Percentage
Inpatient	28	35%
Out patient	52	65%
Total	80	100%

FIGURE1:WARD WISE DISTRIBUTION POE TOTAL PATIENTS(n=80)

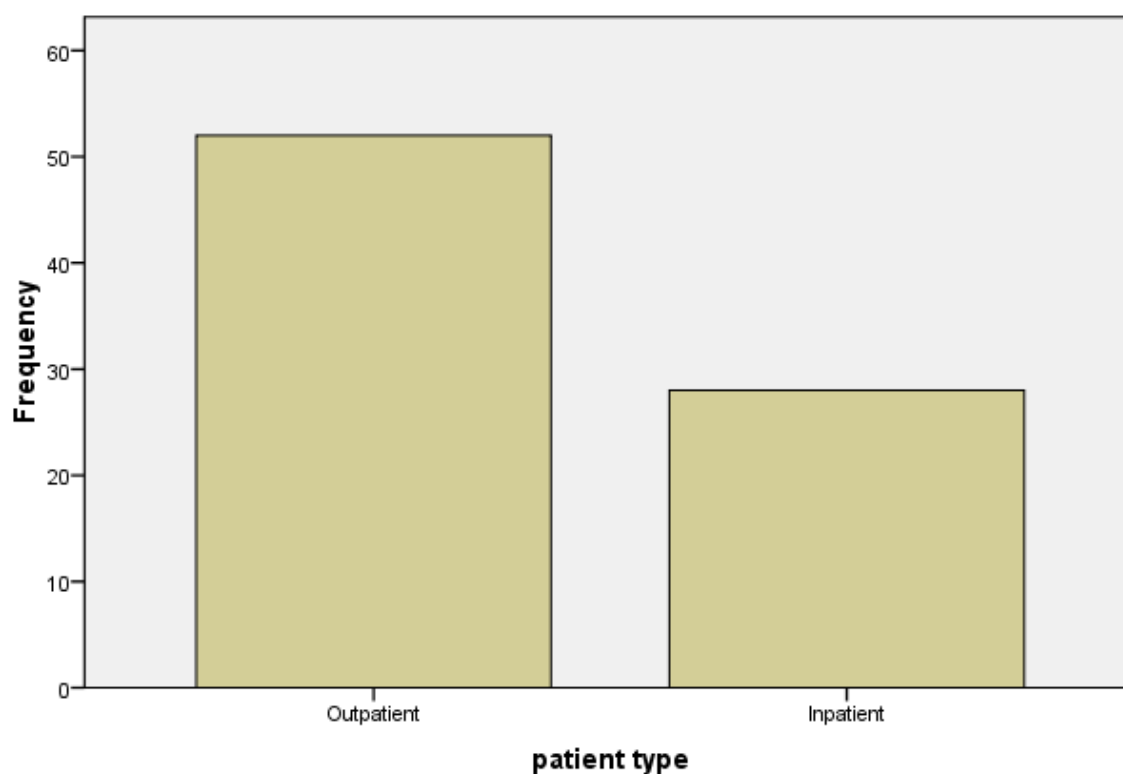


TABLE2: GENDER WISE DISTRIBUTION OF TOTAL PATIENTS(n=80)

Gender	Frequency	Percentage
Males	61	76.2%
Females	19	23.8%
Total	80	100%

FIGURE2:GENDER WISE DISTRIBUTION OF TOTAL PATIENTS (n=80)

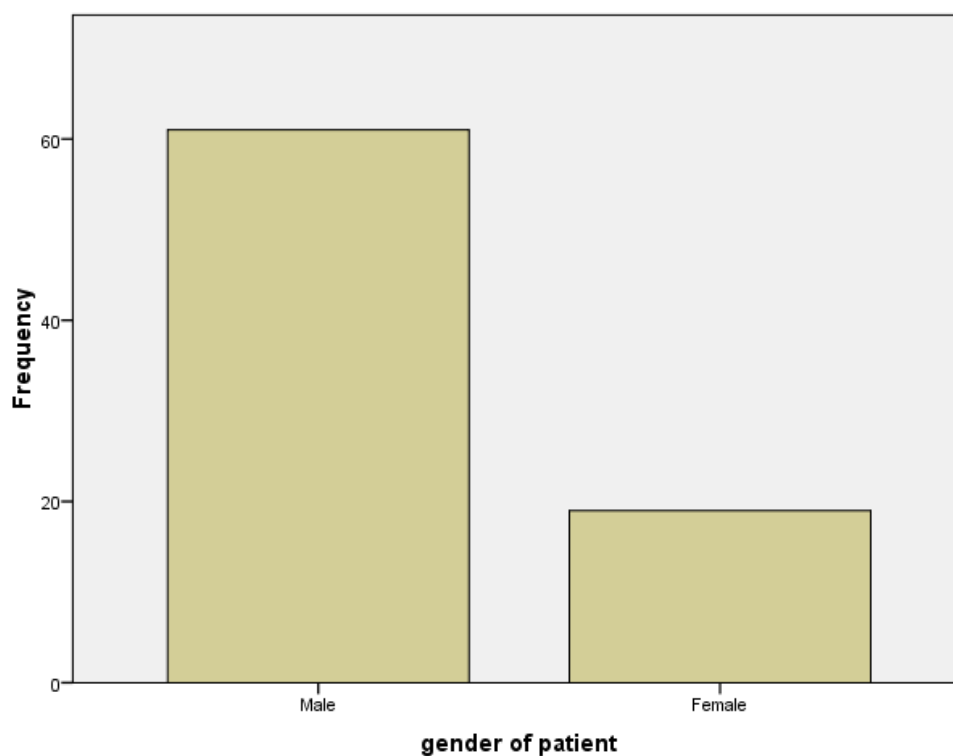


TABLE3: AGE WISE DISTRIBUTION OF PATIENT (n=80)

Age group	Frequency	Percentage
16-30	9	11.25%
31-45	18	22.5%
46-60	33	41.25%
61-75	20	25%
Total	80	100%

FIGURE3: AGE WISE DISTRIBUTION OF TOTAL PATIENTS(n=80)

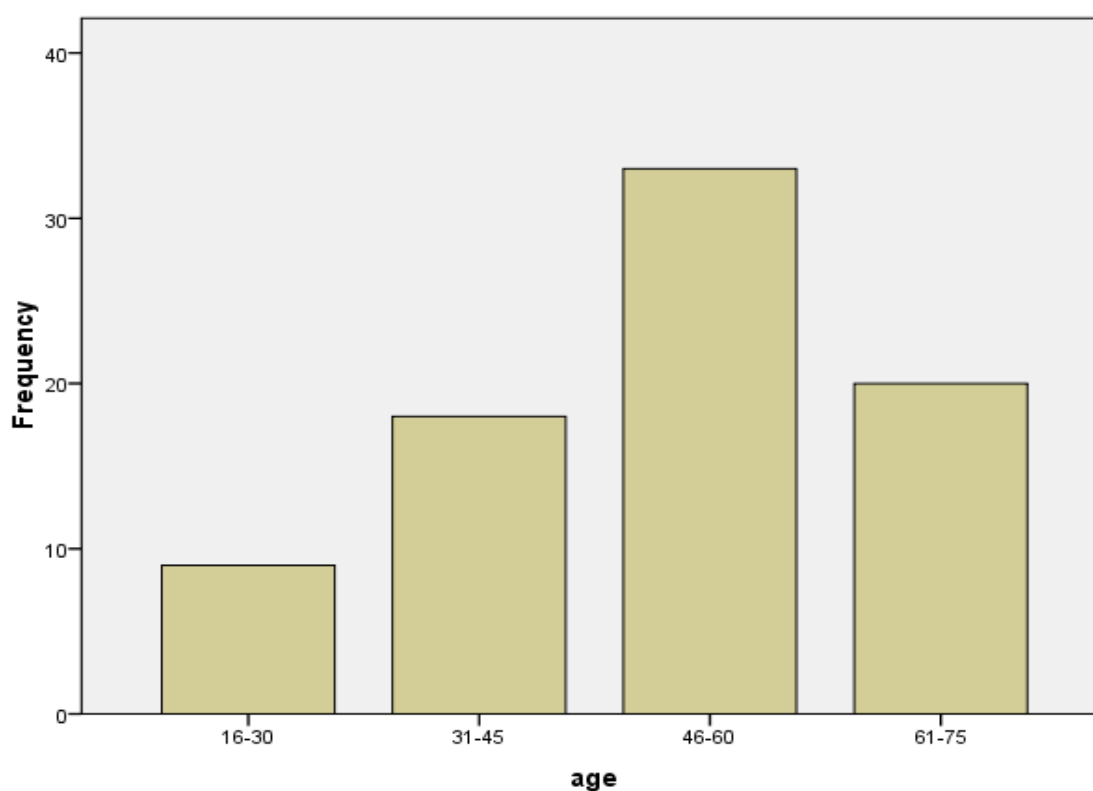


TABLE4:SMOKING HABIT OF TOTAL PATIENTS (n=80)

Smoking habit	Number of patient	Percentage
Smokers	41	51.2
Non-smokers	39	48.8
Total	80	100%

FIGURE4: SMOKING HABIT OF TOTAL PATIENTS (n=80)

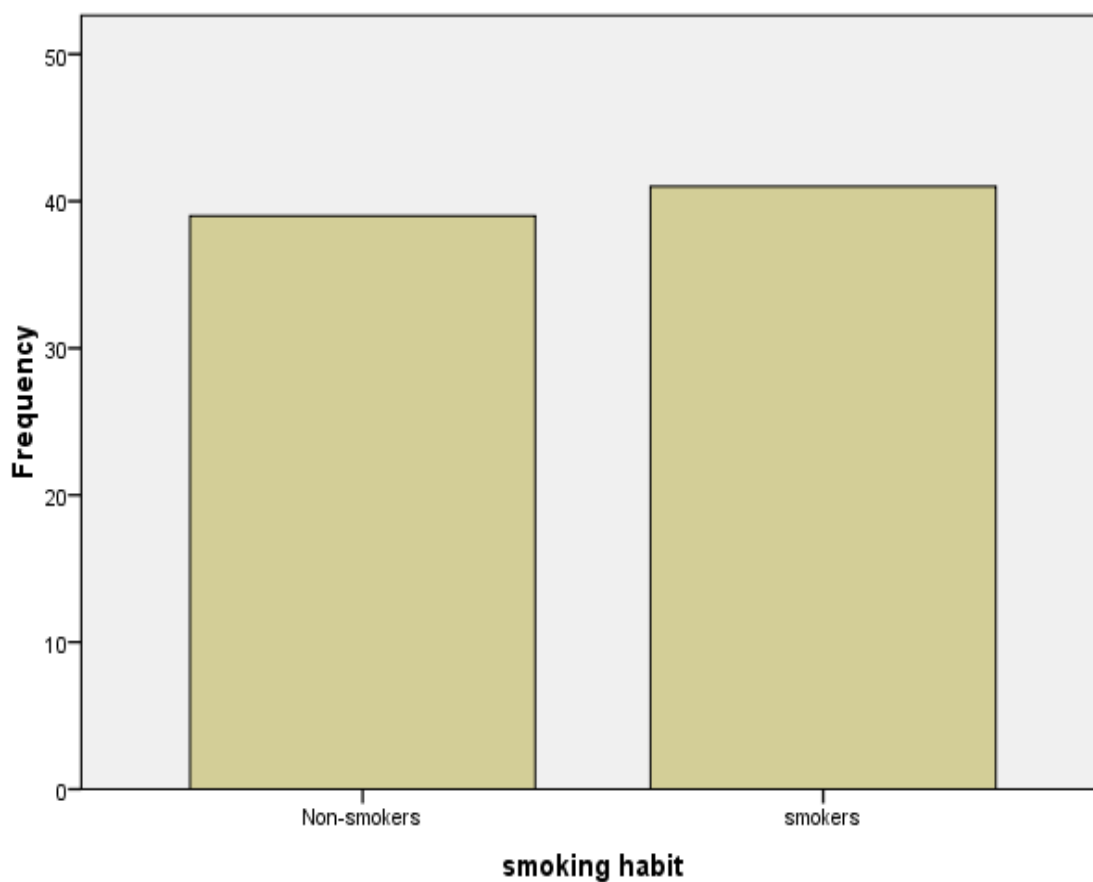


TABLE5: MARITAL STATUS OF THE PATIENTS (n=80)

STATUS	No.of patiets	Percentage
Married	73	91.2%
single	7	8.8%
Total	80	100%

FIGURE5: MARITAL STAUS OF PATIENTS (n=80)

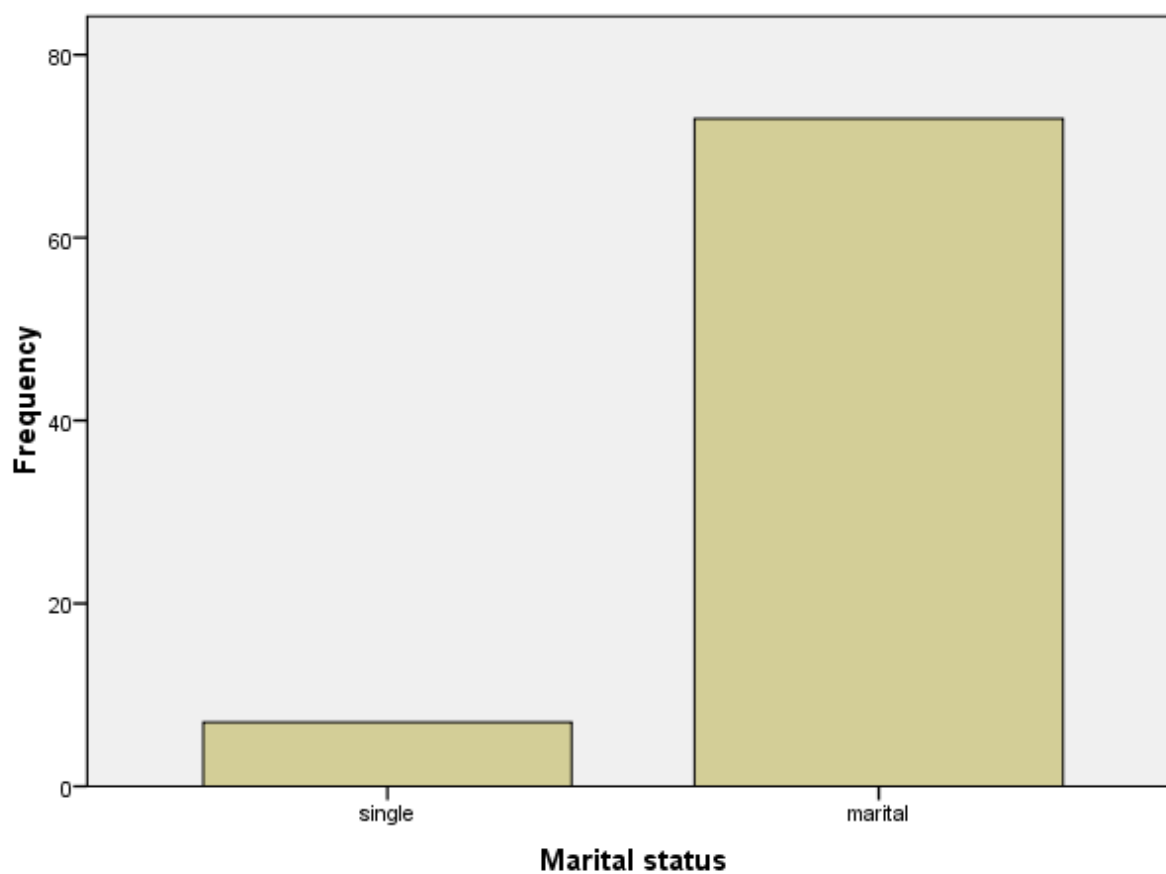


TABLE6: TYPES OF TUBERCULOSIS DIAGNOSED (n=80)

Type of TB	Frequency	Percentage
Pulmonary TB	63	78.8%
Pleural TB	11	11.8%
Rib TB	2	2.5%
Meningitis TB	3	3.8%
Lymph TB	1	1.2%
Total	80	100%

FIGURE6: TYPES OF TUBERCULOSIS DIAGNOSED (n=80)

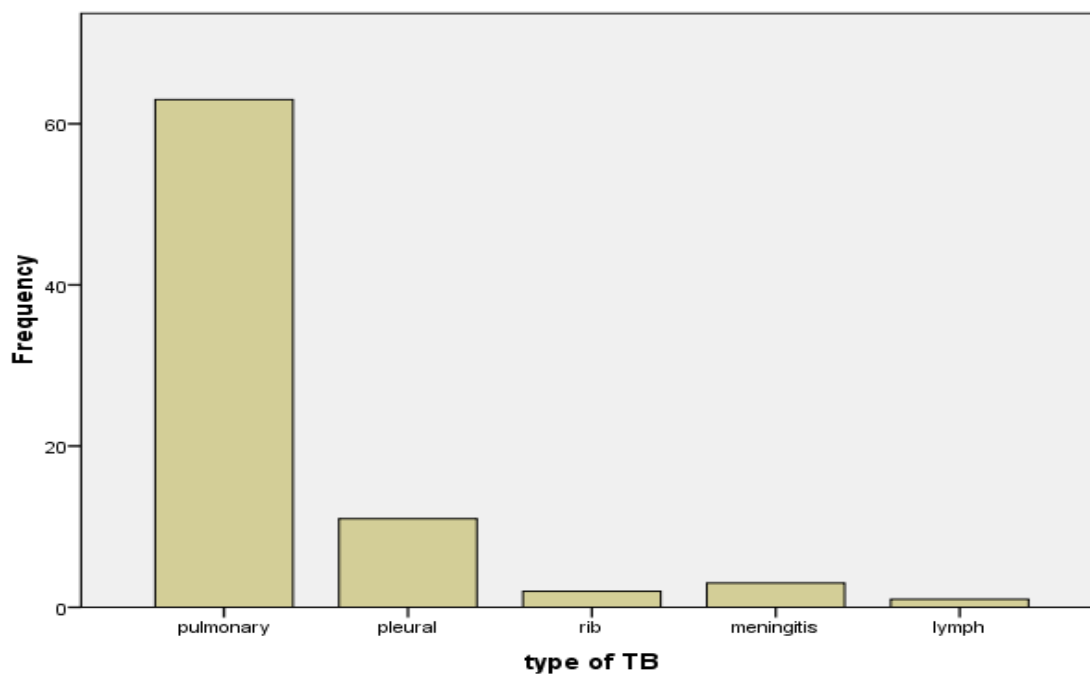


TABLE 7: EDUCATIONAL STATUS OF TOTAL PATIENTS (n=80)

Education	Frequency	Percentage
Illeterate	25	31.2%
School	31	38.8%
Pre-university	18	22.5%
University	6	7.5%

FIGURE 7: EDUCATIONAL STATUS OF TOTAL PATIENTS(n=80)

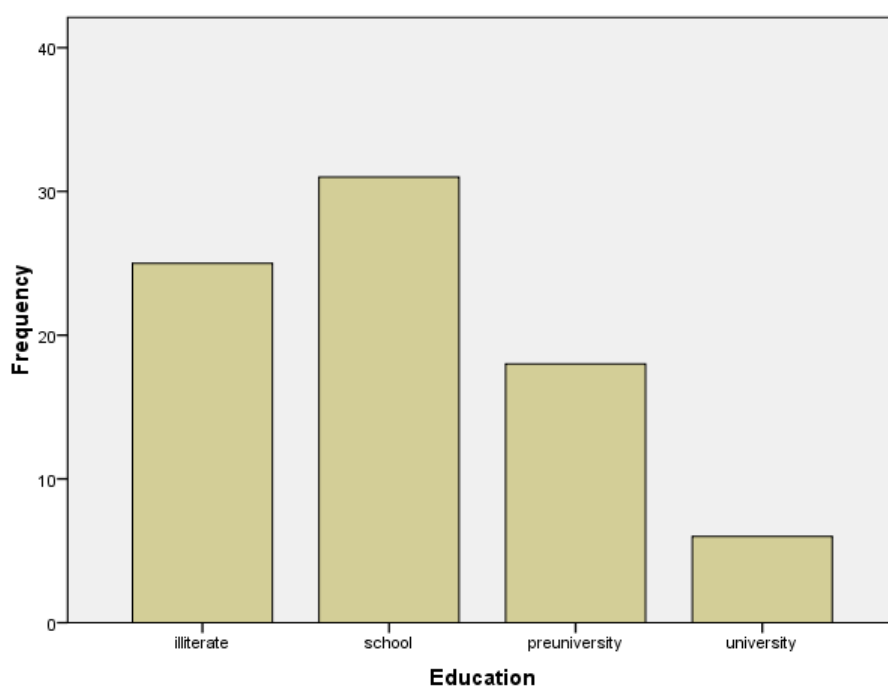


TABLE 8: OCCUPATIONAL STATUS OF TOTAL PATIENTS(n=80)

Occupation	Frequency	Percentage
Daily wager	17	21.2%
Student	3	3.8%
Business	11	13.8%
Farmer	18	22.5%
Unemployed	18	22.5%
Privet services	13	16.2%
Total	80	100%

FIGURE 8: OCCUPATIONAL STATUS OF TOTAL PATIENCE(n=80)

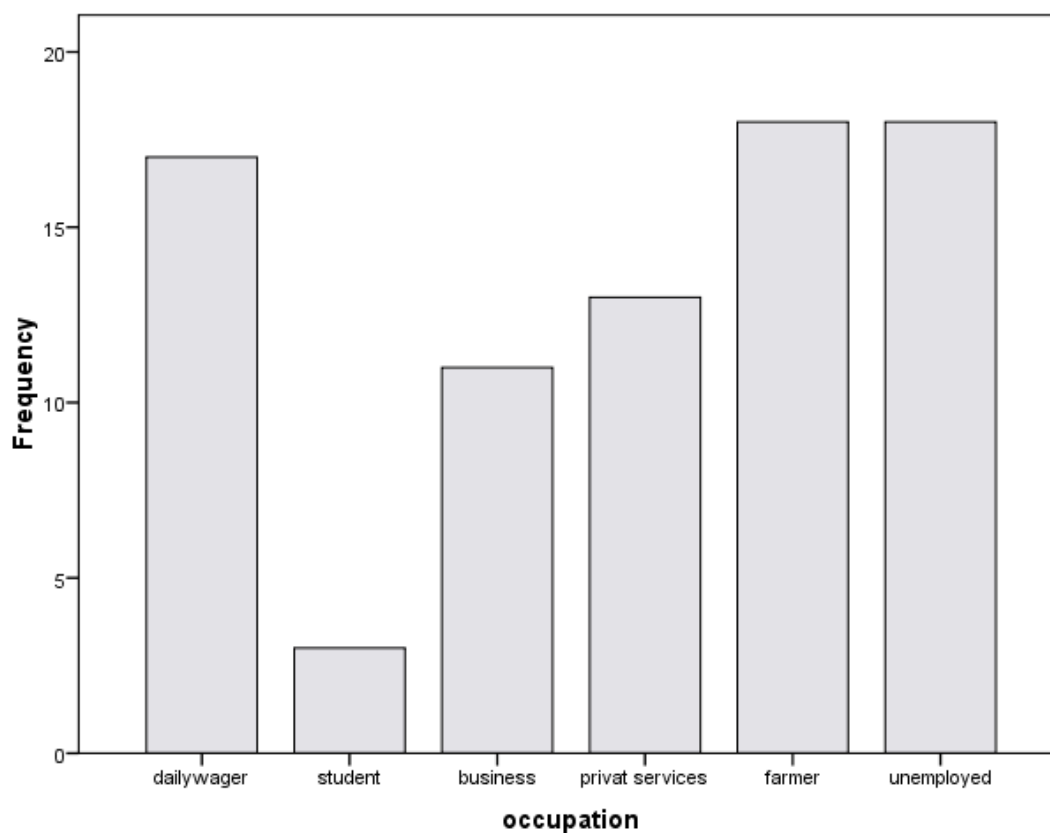


TABLE 9: SIGN AND SYMPTOMS OF TOTAL PATIENTS (n=80)

Symptoms	Frequency	Percentage
Cough	58	72.5%
Breathing difficulty	27	34%
Chest pain	24	30%
Fever	42	52.5%
Loss of appetite	30	38%
Weight loss	32	40%
Haemoptysis	19	24%
Others	18	23%

FIGURE 9: SIGN AND SYMPTOMS OF TOTAL PATIENTS (n=80)

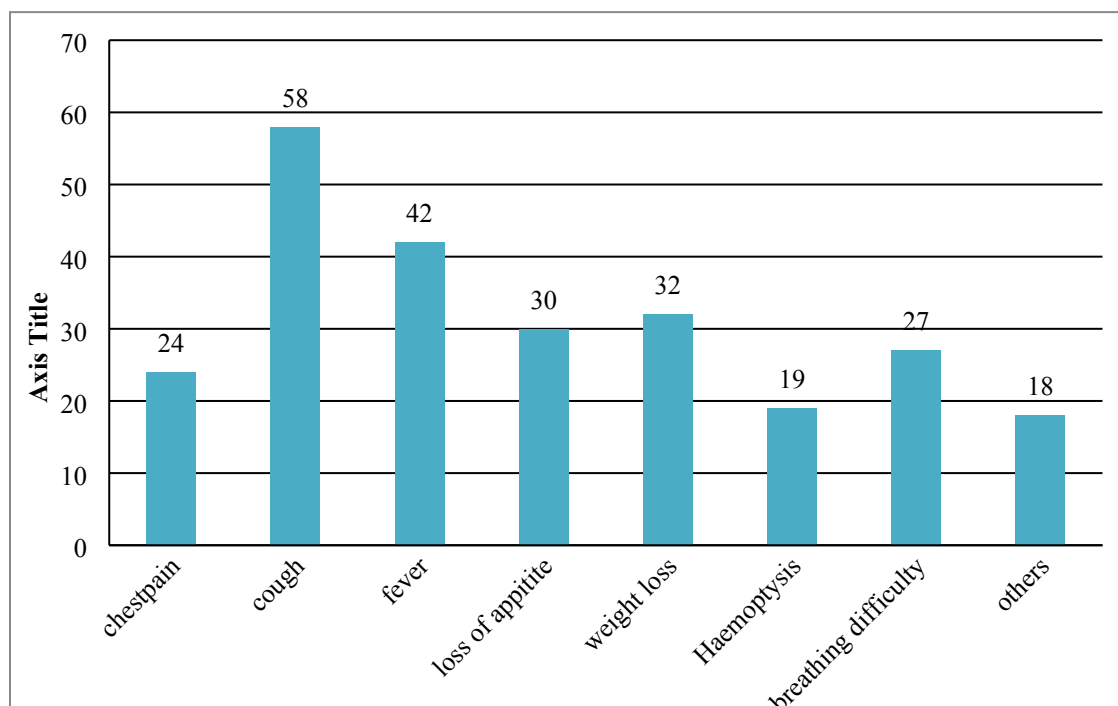


TABLE10: REASON FOR NON-COMPLIANCE (n=80)

Reason	No of patients	Percentage
Forgetfulness	20	25%
Financial	8	10%
Side effects	8	10%
Phase of chemotherapy	13	16.25%
Additional drug	10	12.5%
Feeling well	21	26.25%

FIGURE10: REASON FOR NON-COMPLIANCE (n=80)

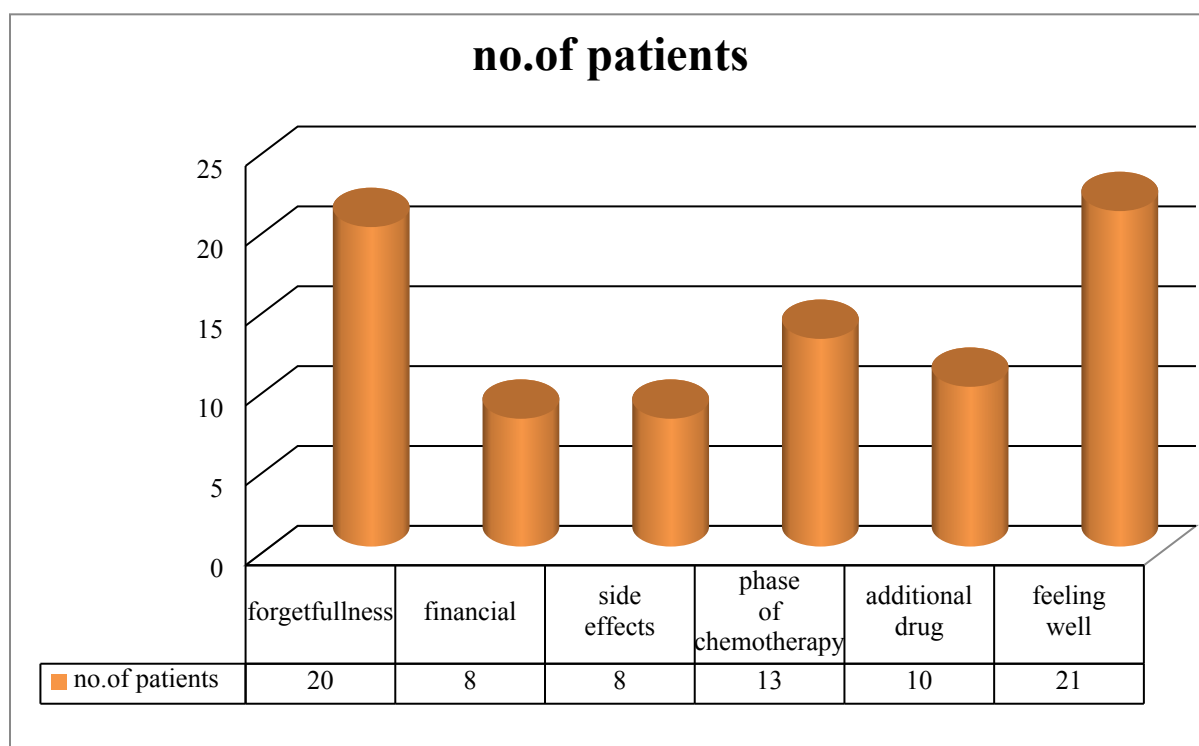


TABLE 11: DISTRIBUTION OF PATIENTS WHO DEVELOPED ADR (n=80)

ADR Occurence	Frequency	Percentage
ADR developers	21	26.26%
ADR non-developers	59	73.75%

FIGURE 11: DISTRIBUTION OF PATIENTS WHO DEVELOPED ADR (n=80)

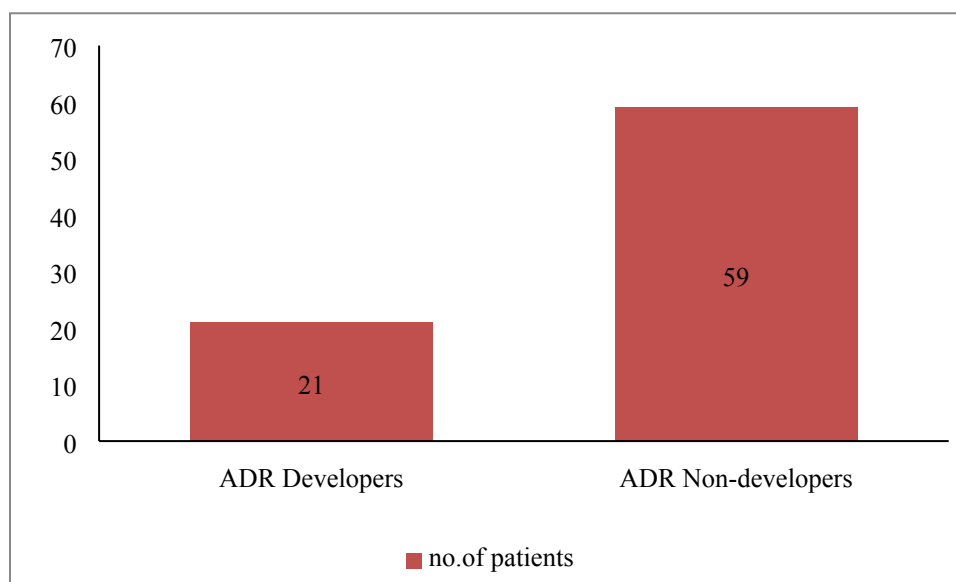


TABLE 12: TYPE OF ADR DEVELOPED (n=21)

S.NO	TYPE OF ADR	FREQUENCY	PERCENTAGE(%)
1	Abdominal pain	3	14.3%
2	Skin rashes	6	28.6%
3	Chest pain	1	4.8%
4	Vomiting/ Elevated liver enzyme	8	38%
5	Numbness of feet	3	14.3%

FIGURE 12: TYPE OF ADR DEVELOPED (n=21)

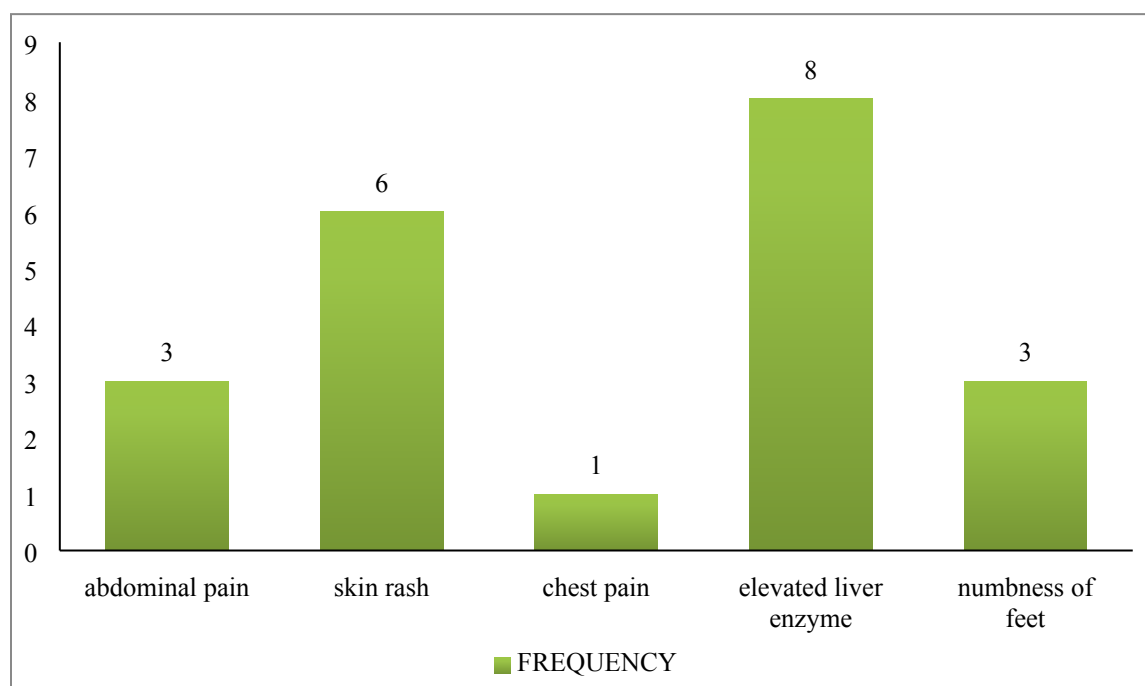


TABLE 13: DEVELOPMENT OF ADR IN EACH FOLLOW UP (n=21)

S.NO		NO OF PATIENT	PERCENTAGE(%)
1	visit1	15	71.5%
2	visit2	4	19%
3	visit3	2	9.5%

FIGURE13 : DEVELOPMENT OF ADR IN EACH FOLLOW UP (n=21)

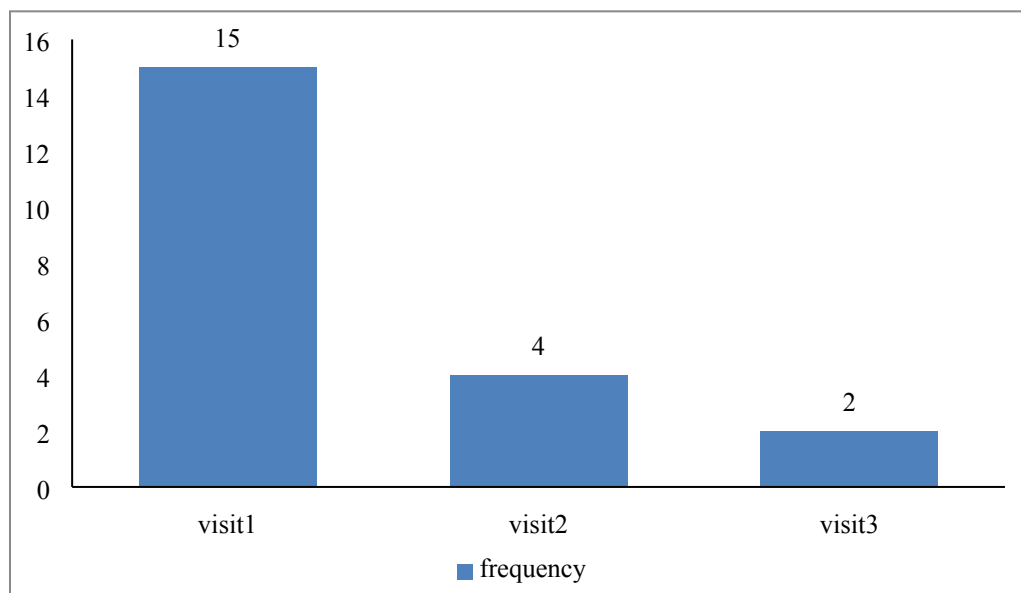


TABLE 14: DISTRIBUTION OF LEVEL OF MEDICATION ADHERENCE AMONG STUDY POPULATION (n=80)

S.NO	ADHERENCE	BASELINE	FOLLOW UP I	FOLLOW UP II
1	Low adherence (7-11)	25 (31.25%)	24(30%)	16 (20%)
2	Medium adherence (4-6)	36 (45%)	39(48.75%)	37 (46.25%)
3	High adherence (0-3)	19(23.75%)	17 (21.25%)	27 (33.75%)

FIG 14: DISTRIBUTION OF LEVEL OF MEDICATION ADHERENCE AMONG STUDY POPULATION (n=80)

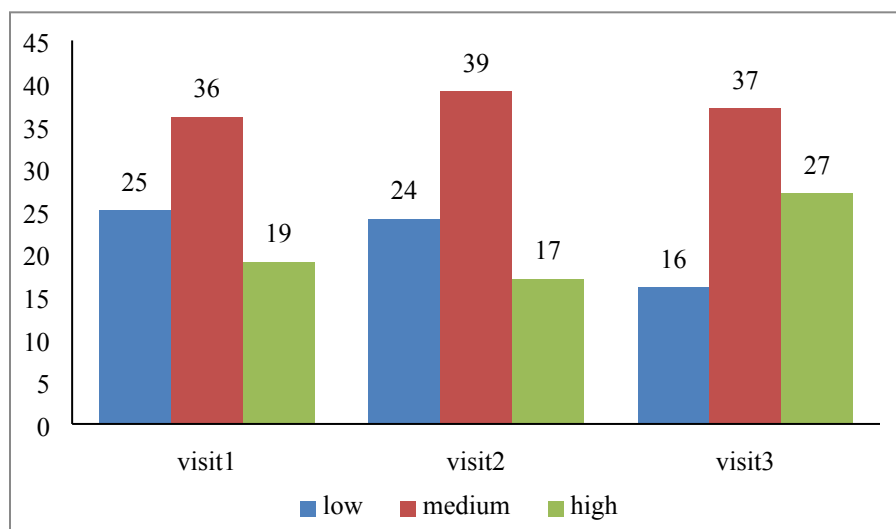


TABLE 15 :BASELINE MEDICATION ADHERENCE SCORE VS VISIT1 AND VISIT2

	Mean	Std .deviation	P value	Significance
Visit1	1.64	.75	.008	Significant
Visit2	1.98	.67	.000	Significant

FIGURE 15 :BASELINE MEDICATION ADHERENCE SCORE VS FOLLOW UP I

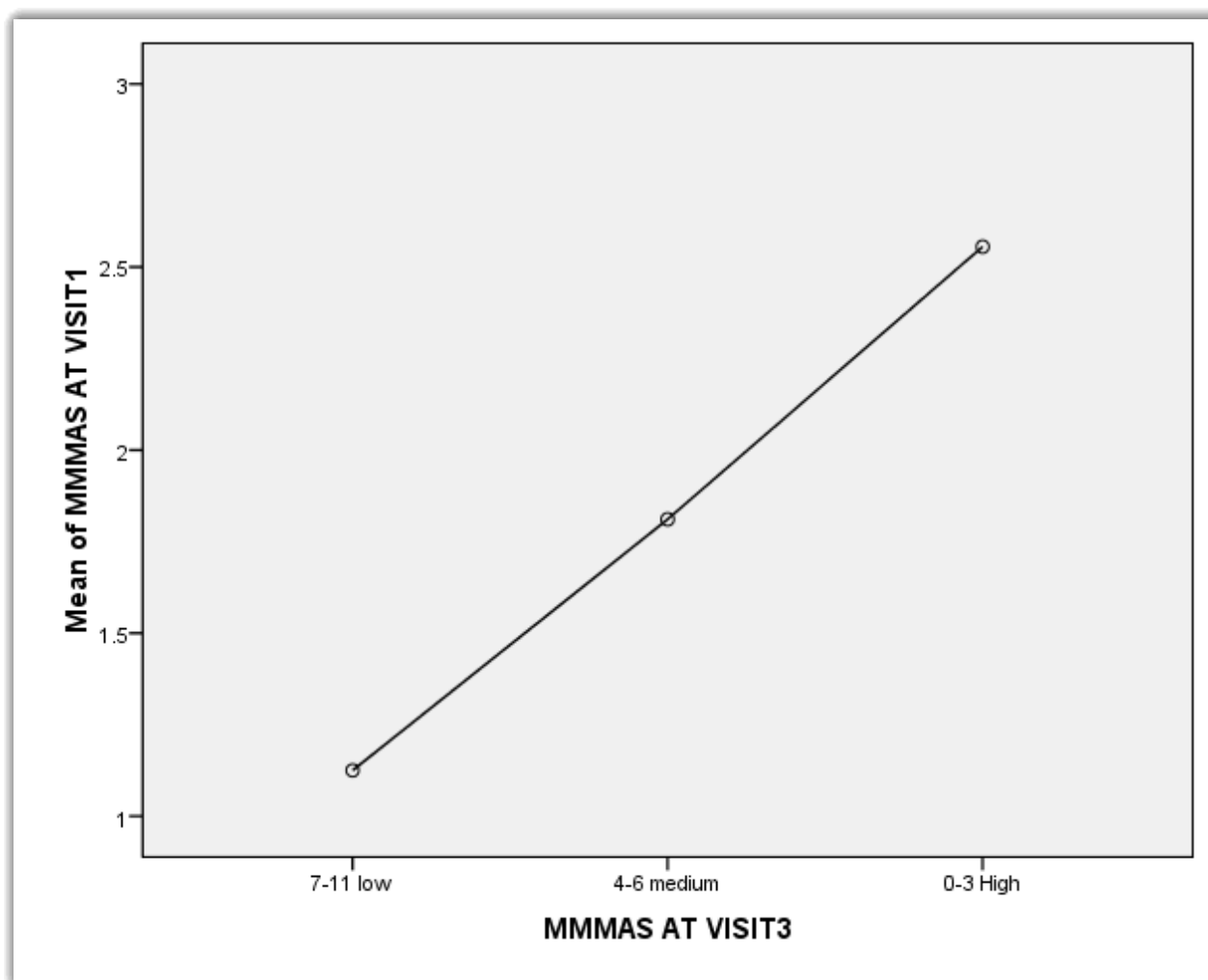


FIGURE 16 :BASELINE MEDICATION ADHERENCE SCORE VS FOLLOW UP II

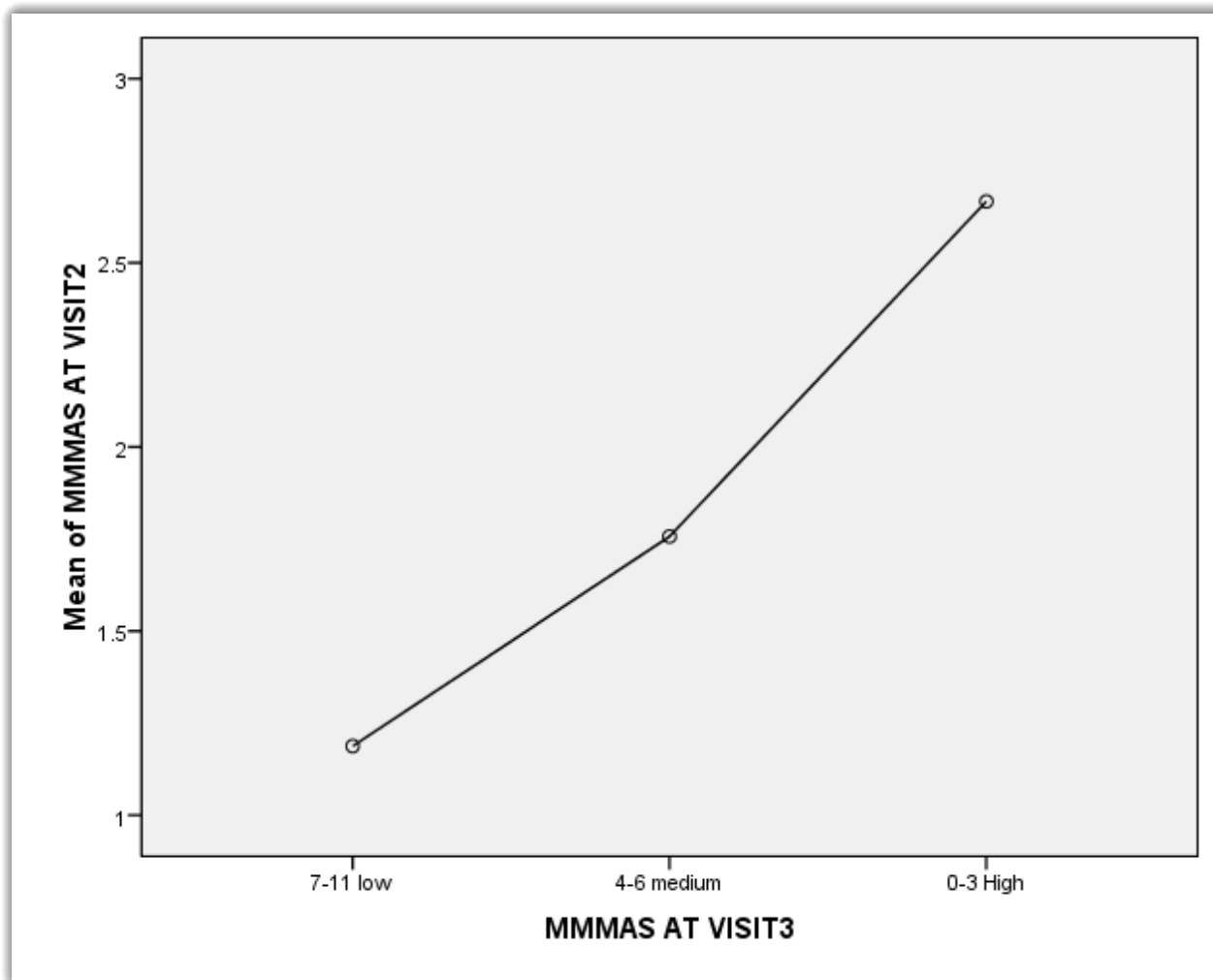


TABLE16 : Medication adherence on TB to demographic characteristics (n=80)

		n	%	Mean	SD	P value
Gender	Male	61	76%	1.62	.818	.000
	Female	19	24%			
Age	16-30	9	11.25%	-.400	1.165	.003
	31-45	18	22.5%			
	46-60	33	41.25%			
	61-75	20	25%			
Type of TB	Pulmonary	63	78.8%	1.050	1.113	.000
	Pleural	11	11.8%			
	Rib	2	2.5%			
	Meningitis	3	3.8%			
	Lymph	1	1.2%			
Education	Illiterate	25	31.2%	1.67	.756	.0
	School	31	38.8%			
	Pre-university	18	22.5%			
	University	6	7.5%			
Marital status	single	7	91.2%	.487	.763	.000
	Marital	73	8.8%			
Patient type	Inpatient	52	35%	1.050	.825	.000
	Outpatient	28	65%			
			51.2			

Smoking status	Smokers	39		.888	.871	.000
	Non smokers	41	48.8			
Occupation	Daily wager	17	21.2%	-1.425	1.954	.000
	Student	3	3.8%			
	Business	11	13.8%			
	private – service	18	22.5%			
	Farmer	18	22.5%			
	Unemployed	13	16.2%			

TABLE 17: DISTRIBUTION OF KNOWLEDGE LEVEL AMONG STUDY POPULATION (n=80)

S.NO	PATIENT KNOWLEDGE	VISIT 1	VISIT 2	VISIT 3
1	Poor knowledge (0-3)	42 (52.5%)	19(23.75%)	11 (13.75%)
2	Moderate knowledge (4-6)	25 (31.25%)	44(55%)	26 (32.5%)
3	Good knowledge (7-10)	13(16.25%)	17 (21.25%)	43 (53.75%)

FIGURE 17: DISTRIBUTION OF KNOWLEDGE LEVEL AMONG STUDY POPULATION (n=80)

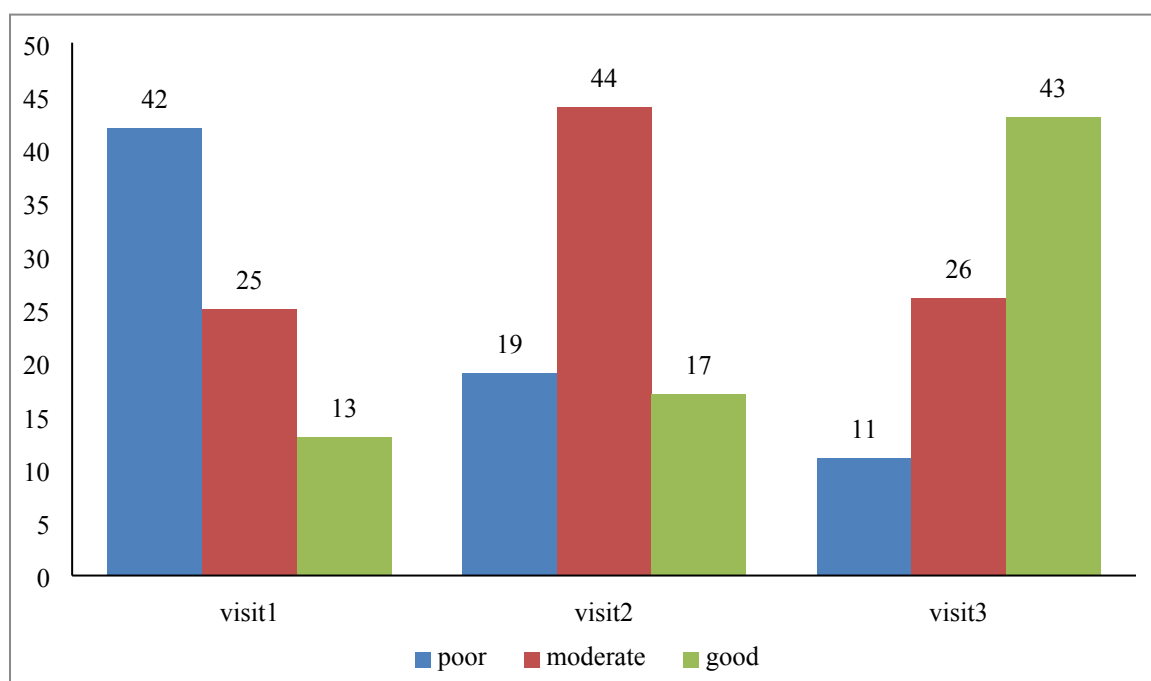


TABLE 18: Knowledge score of visit 1 and visit 2 by visit 3 knowledge score

	Mean	Std .deviation	P value	Significance
Visit1	1.64	.75	.008	Significant
Visit2	1.98	.67	.000	Significant

FIG 18: Knowledge score of visit 1 by visit 3 knowledge score

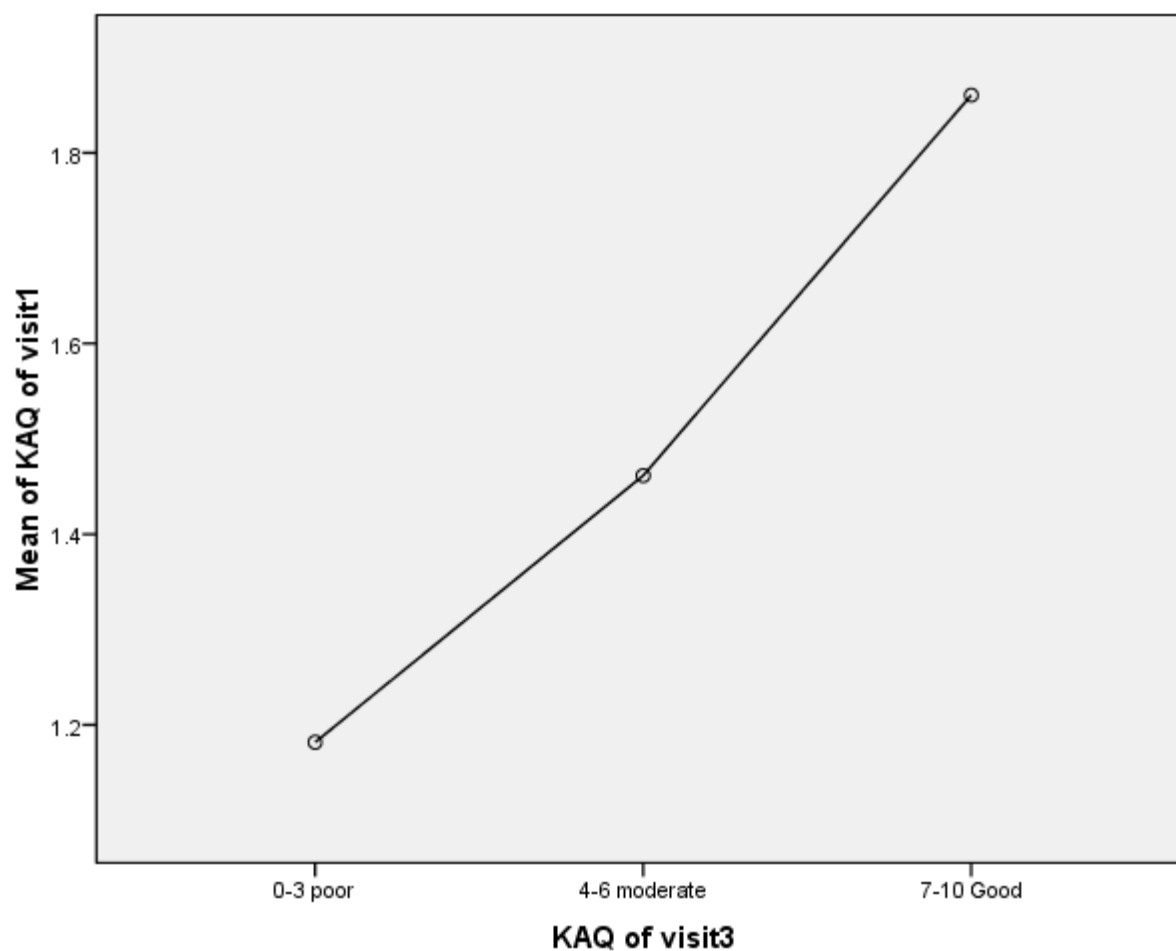


FIG19 : Knowledge score of visit 12 by visit 3 knowledge score

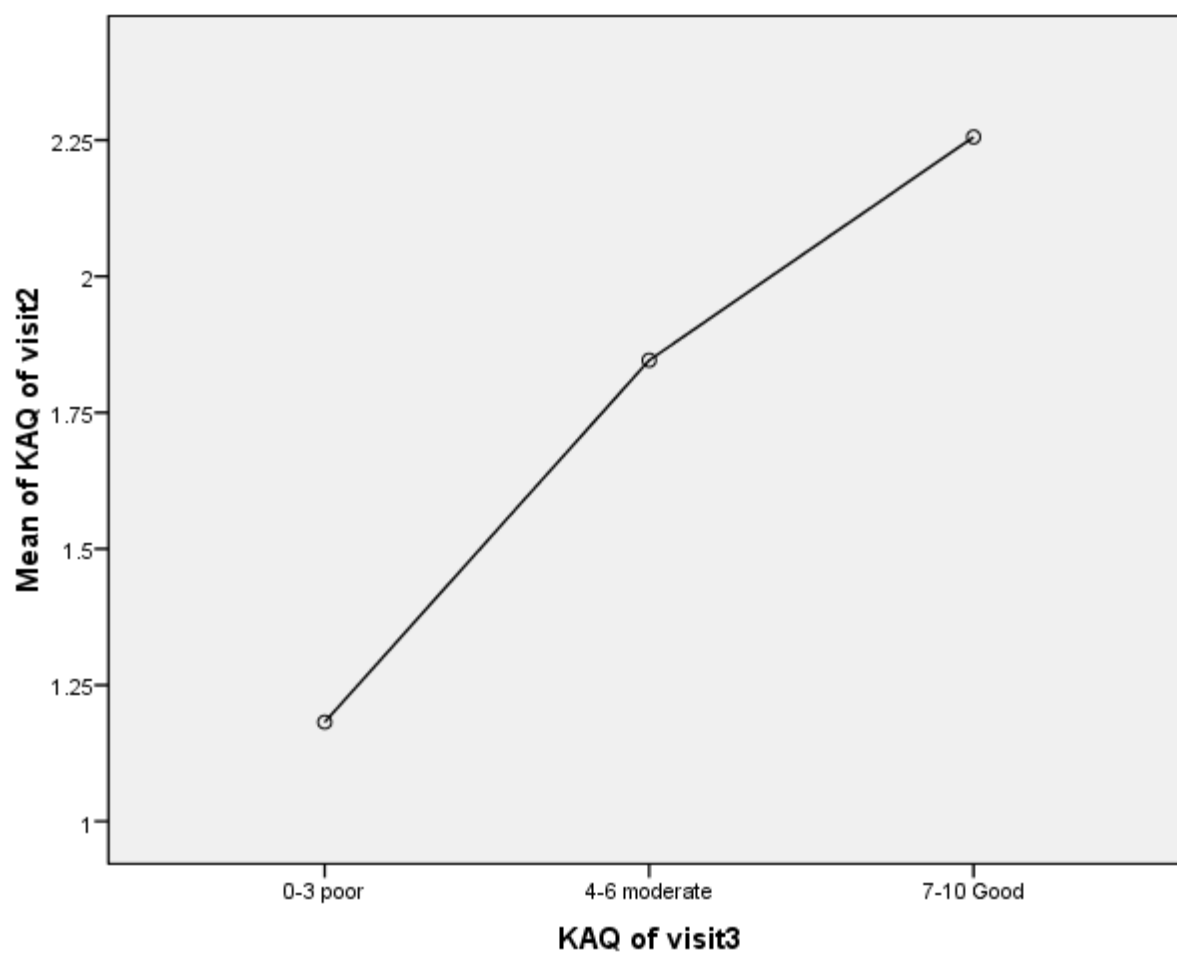


TABLE 19: Knowledge on TB to demographic characteristics (n=80)

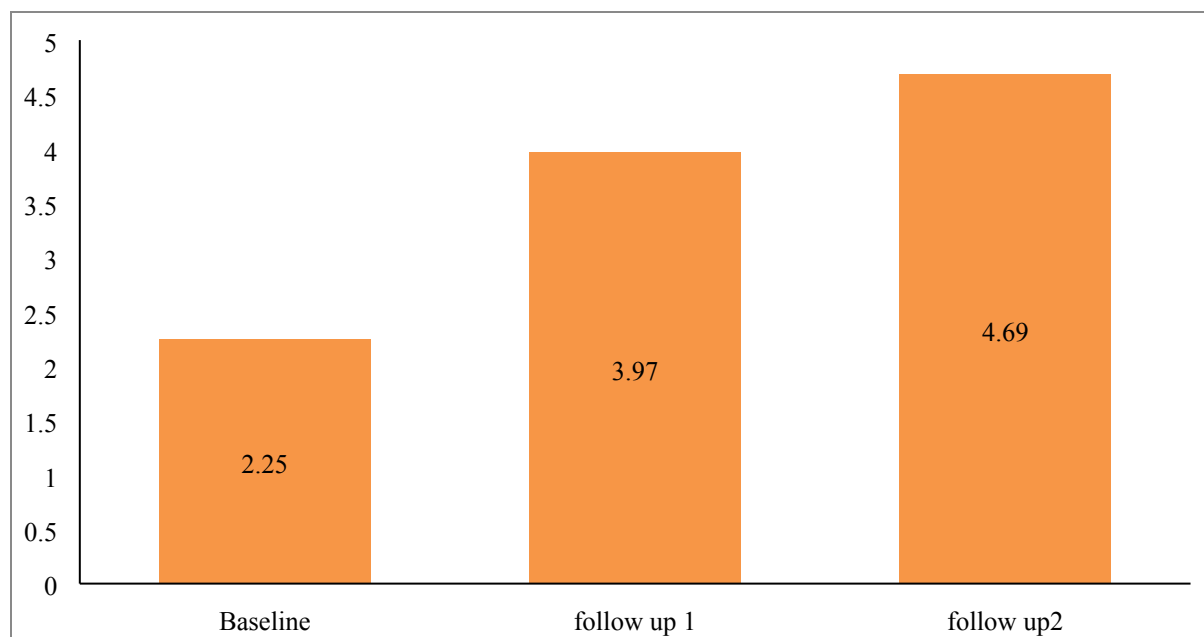
Independent variables	Variable categories	n	%	Mean	SD	P value
Gender	Male	61	76%	.900	.789	.000
	Female	19	24%			
Age	16-30	9	11.25%	-.662	1.169	.000
	31-45	18	22.5%			
	46-60	33	41.25%			
	61-75	20	25%			
Type of TB	Pulmonary	63	78.8%	.788	1.110	.000
	Pleural	11	11.8%			
	Rib	2	2.5%			
	Meningitis	3	3.8%			
	Lymph	1	1.2%			
Education	Illiterate	25	31.2%	1.16	.750	.042
	School	31	38.8%			
	Pre-university	18	22.5%			
	University	6	7.5%			
Marital status	Single	7	91.2%	.225	.746	.009
	Marital	73	8.8%			

Patient type	Inpatient	52	35%	.788	.852	.000
	Outpatient	28	65%			
	Smokers	39	51.2	.625	.802	.000
	Non smokers	41	48.8			
Occupation	Daily wager	17	21.2%	1.688	1.940	.000
	Student	3	3.8%			
	Business	11	13.8%			
	Farmer	18	22.5%			
	Unemployed	18	22.5%			
		13	16.2%			

TABLE 20: Comparison of Knowledge and Medication adherence score

	Mean	Standard deviation	P value	significance
Baseline	2.25	.697	0.00	Significant
Follow up 1 st	3.97	.811	0.00	Significant
Follow up 2 nd	4.69	.882	0.009	Significant

FIG 20: Comparison of Knowledge and Medication adherence score



CONCLUSION

This study was principally emphasized in absolute care of Tuberculosis patients throughout their intensive phase of therapy by providing a knowledge based approach to improve the drug adherence and reducing severity of drug related problems.

Entirely 80 patient were included in the study. Tuberculosis was predominant in males. In this study found that TB occurred chiefly in age group '46-60'. Majority of them had PTB. Most of the patients presented with cardinal sign of TB such as cough. In my study all the patients got counselling with the help of pamphlet and knowledge was assessed by giving the knowledge assessment questionnaire and the medication adherence assessed by Morisky medication adherence scale.

Patient education and medication counseling are essential components in the management of TB. Medication adherence can be achieved by educating the patient about the disease and drugs and their use,

In conclusion, patient education had most impact on medication adherence, Medication adherence was improved after counseling of patients. By this, the study concluded that patient education and medication counseling improved adherence and improved their therapy outcome.

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